

## **REMARKS**

Claims 38-56 and 76-86 are pending in the patent application. New claims 87-168 have been added to the application. Claims 38, 41, 42, 45-47, 52, 76, and 79 have been amended. Claims 38 and 76 have been amended to more clearly indicate that the second layer is adapted to be removed, while the first layer remains sealed to the package. Claims 41 and 79 have been amended to correct grammatical errors. Claims 42, 46, and 47 have eliminated the phrase “the step” to be consistent with the other dependent claims and to make clear that the claims are not “step-plus-function” claims. Claim 45 has been amended to be dependent on dependent claim 44. Claim 52 has been amended to more clearly recite that the portion comprising a polyolefin or a polyvinyl chloride overwrap is the portion that is substantially permeable to oxygen as recited in claim 38. No new matter has been entered. After entry of these amendments, claims 38-56, 76-86, and 87-168 are present in the patent application.

### **I. Information Disclosure Statement**

Applicants are filing concurrently herewith a Third Information Disclosure Statement (IDS) and Form PTO-1449. Applicants respectfully request that these references be made of record.

### **II. 35 U.S.C. § 103(a) Rejections**

#### **A. Embodiments/Methods of the Present Invention**

The Applicants are submitting herewith evidence in the form of a 37 C.F.R. §1.132 declaration by one of the co-inventors Mr. Gary R. DelDuca (“the DelDuca Declaration”) (Exhibit A) to assist in explaining the present invention and showing the non-obviousness of the invention.

The present invention is directed to novel modified atmosphere packages and methods of manufacturing the same. For example, independent claims 38, 76, 119, 138, and 157 recite, *inter alia*, “a first layer having at least a portion being substantially permeable to oxygen”, “a second layer being substantially impermeable to oxygen”, and a low oxygen environment that includes from about 0.1 to about 0.8 vol. % carbon monoxide (CO). Independent claims 87 and 103 recite, *inter alia*, “sealing the layer substantially impermeable to oxygen to the package”, “removing the layer substantially impermeable to oxygen”, “sealing a layer having at least a

portion being substantially permeable to oxygen”, and a low oxygen environment that includes from about 0.1 to about 0.8 vol. % CO.

The modified atmosphere packages and methods of manufacturing the same have several advantages as follows: (a) the “seasoning” period of the raw meat may be reduced or eliminated; (b) the ability to obtain consistent blooming with cuts off pigment-sensitive meats (*e.g.*, round bone) is improved; and (c) the ability to avoid “fixing” the color of the meat pigment to red. *See, e.g.*, page 11, line 29 - page 12, line 15; page 13, lines 11-17 of the application and DelDuca Decl. ¶ 4.

The “seasoning” period is the time period needed to diffuse the oxygen so that the meat has the ability to fully bloom. Page 3, lines 17-19 of the application and DelDuca Decl. ¶ 5. Trays, such as polystyrene foam trays, have a substantial amount of oxygen contained in its cellular structure that results in a time period of as long as about 5 to about 6 days to diffuse the oxygen contained in its cellular structure. Page 3, lines 21-23 of the application and DelDuca Decl. ¶ 5. If a foam tray is not used, the “seasoning” period can be reduced to one or two days. Page 3, lines 24-25 of the application and DelDuca Decl. ¶ 5. The reduction or elimination of the seasoning period “allows the meat to be displayed for retail sale much sooner than in existing low oxygen packaging systems.” Page 11, line 32 - page 12, line 2 of the application and DelDuca Decl. ¶ 5. Seasoning periods are not desired by the retailers or packers because of the “need to store and maintain the meat-filled packages for an extended duration before being opened for retail sale.” Page 3, lines 27-28 of the application and DelDuca Decl. ¶ 5.

The present invention does not “fix” the color of the meat pigment to red with its use of CO, but rather the meat pigment tends to turn brown in a natural time period. *See* page 12, lines 10-12 of the application and DelDuca Decl. ¶ 6. It is important to prevent the meat color from being “fixed” because it is unsafe (and potentially dangerous) to consume a piece of meat that has a bright red color that consumers associate with freshness, but has an unacceptable amount of bacteria. DelDuca Decl. ¶ 7.

The present invention “surprisingly allows the meat pigment to convert to metmyoglobin in a similar fashion as fresh, raw meat in a retail environment.” Page 12, lines 7-10 of the application and DelDuca Decl. ¶ 7. Specifically, the color on the meat after exposure to ambient

temperature degrades in a fashion not beyond the point of microbial soundness as if the CO had never been added to the modified packaging system. DelDuca Decl. ¶ 7.

The meat used in the modified atmosphere packaging of the present invention substantially maintains its color during the shipping process because the package has a modified atmosphere that includes from about 0.1% to about 0.8 vol. % carbon monoxide. DelDuca Decl. ¶ 8. In one method, after removal of the substantially impermeable layer, the CO is lost to the atmosphere. See page 12, lines 2-6 of the application and DelDuca Decl. ¶ 8. The CO may be lost to the atmosphere through the first layer that includes a portion that is substantially permeable to oxygen. *Id.* and page 13, lines 5-10 of the application. This allows the conversion of the carboxymyoglobin to oxymyoglobin by using the oxygen from the air. Page 12, lines 4-7 of the application and DelDuca Decl. ¶ 8. The “gas mixture used in the modified atmosphere packages of the present invention, after removal, allows the carboxymyoglobin to convert to oxymyoglobin and then to metmyoglobin (brown) in a natural time period.” Page 12, lines 3-5 of the application and DelDuca Decl. ¶ 8. Thus, the color of the meat is not “fixed” in the present invention.

**B. A *Prima Facie* Case Has Not Been Presented with Respect to Independent Claims 38 and 76**

The two pending independent claims (claims 38 and 76) include, *inter alia*, (a) a “first layer having at least a portion being substantially permeable to oxygen”, (b) “a second layer being substantially impermeable to oxygen”, and (c) a low oxygen environment that includes from about 0.1 to about 0.8 vol. % carbon monoxide (CO).

None of the applied references includes, *inter alia*, such limitations that are recited in independent claims 38 and 76. As acknowledged in the Office Action, U.S. Patent No. 4,522,835 to Woodruff (“Woodruff”) is “silent in teaching any particular package or method of packaging for sale or consumption as recited in claims 38 and 76.” U.S. Patent No. 5,686,127 to Stockley III (“Stockley”) does not disclose using CO in its meat package.

As acknowledged in the Office Action, the article entitled “The storage life of beef and pork packaged in an atmosphere with low carbon monoxide and high carbon dioxide” from *Meat Science* to Sorheim (“Sorheim”) does not disclose a packaging system having (a) “a first layer

having at least a portion being substantially permeable to oxygen”, and (b) “a second layer being substantially impermeable to oxygen” as recited in independent claims 38 and 76.

Rather, Sorheim discloses several meat packaging systems consisting of trays wrapped in polymeric film. Sorheim at page 158. The Sorheim meat packaging systems include the use of 0.4% CO, 60% CO<sub>2</sub>, and 40% N<sub>2</sub>. *Id.* Sorheim also discloses the use of CO in amounts of approximately 0.3 to 0.5%. *Id.* at page 157.

Unlike the present invention, the Sorheim meat packaging systems do not address the problem of “fixing” the meat color because the CO remains in the Sorheim sealed packaging system until the polymeric film is removed by the customer. In other words, during retail display, the CO remains in contact with the meat in the Sorheim sealed package. *See, e.g., id.* at page 157 (Sorheim discloses that “a low CO/high CO<sub>2</sub> atmosphere is effective for preserving retail-ready meat.”). The Sorheim meat packaging systems, therefore, can undesirably fix the color of the meat pigment to red.

There is no teaching or suggestion to combine the references of Woodruff, Sorheim, and Stockley. The mere fact that references can be combined together or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680 (Fed. Cir. 1990). “When a rejection depends on a combination of prior art references, there must be some teaching, suggestion, or motivation to combine the references.” *Rouffet*, 149 F.3d at 1355, 47 U.S.P.Q.2d at 1456, (*citing In re Geiger*, 815 F.2d 686, 688, 2 U.S.P.Q.2d 1276, 1278 (Fed. Cir. 1987)). Evidence of a suggestion, teaching, or motivation to combine “must be clear and particular.” *Ex parte Maruyama*, 2001 WL 1918556, \*3 (Bd. Pat. App. & Inter. 2001), (*citing C.R. Bard, Inc. v. M3 Sys. Inc.*, 157 F.3d 1340, 1352, 48 U.S.P.Q.2d 1225, 1232 (Fed. Cir. 1998)). None of the applied references addresses the problem of “fixing” the meat color to a bright red color with CO. Preventing the fixing of the meat color is important because it is unsafe (and potentially dangerous) to consume a piece of meat that has a bright red color that consumers associate with freshness, but has an unacceptable amount of bacteria. DelDuca Decl. ¶ 7.

Sorheim not only do not address the problem of fixing the color, but rather discloses that its meat packaging systems with a modified atmosphere of “0.4% CO/60% CO<sub>2</sub>/40% N<sub>2</sub> had a bright stable red colour that lasted beyond the time of spoilage.” Abstract of Sorheim. This is

exactly the problem that the present invention overcomes. Stockley does not mention CO, let alone recognize the problem of fixing the color. Woodruff is also silent on recognizing the problem associated with fixing the color and, furthermore, does not disclose any packaging systems solutions involving CO as recited in the claims.

Thus, there is no motivation to combine these references to address the problem and consequently the solution proposed in the present invention. Additionally, Sorheim, the only applied reference that proposes a packaging system with CO, believes that its packaging solution is effective. *See generally* abstract of Sorheim. The authors of Sorheim, who are members of the Norwegian Food Research Institute or the Norwegian Meat Cooperative, also state that the Norwegian meat industry “is seeking amendments of current EU food regulations relating to the use of CO in MAP [modified atmosphere packaging] of red meats.” Sorheim at pages 157, 158 (noting that the EU as of 1999 does not allow CO in its MAP of meat). Thus, it is clear that Sorheim believes that its meat packaging systems are desirable and there is no teaching or incentive to combine Sorheim with either Stockley, Woodruff, or the combination thereof.

Additionally, the combination of Stockley and Woodruff is also improper. Stockley is totally devoid of any teaching or suggestion of using CO. Rather, Stockley discloses the use of nitrogen, carbon dioxide, or the combination thereof. Col. 5, lines 2-5. Stockley does not disclose a packaging system with CO and it would be pure hindsight to combine Stockley with Woodruff when neither reference mentions the problem addressed in the present invention.

Obviousness cannot “be established using hindsight or in view of the teachings or suggestions of the invention.” *Ex parte Maguire* (Appendix 9), 2002 WL 1801466, \*3 (Bd. Pat. App. & Inter. 2002), (*quoting Para-Ordnance Mfg. Inc. v. SGS Importers Int’l Inc.*, 73 F.3d 1085, 1087, 37 U.S.P.Q.2d 1237, 1239 (Fed. Cir. 1995), *cert. denied*, 519 U.S. 822 (1996)). In other words, the knowledge to combine “*can not* come from the applicant’s invention itself.” *In re Oetiker*, 977 F.2d 1443, 1447, 24 U.S.P.Q.2d 1443, 1446 (Fed. Cir. 1992) (emphasis added).

Thus, the Applicants believe that a *prima facie* case has not been presented with Woodruff, Stockley, Sorheim, or any combination thereof.

### **C. Evidence of Non-Obviousness of Independent Claims 38 and 76**

Assuming, *arguendo*, that a *prima facie* case has been presented (which Applicants believe is not the case), the Applicants are submitting evidence of non-obviousness in the form of

a 37 C.F.R. §1.132 declaration by one of the co-inventors Mr. Gary R. DelDuca (“the DelDuca Declaration”)(Exhibit A) to assist in showing the non-obviousness of the invention.

**i. CO Not Allowed with Fresh Meat in the United States Since At Least 1962**

Carbon monoxide (CO) has not been allowed to be used with fresh meat in the United States for about 40 years.<sup>1,2</sup> The Food and Drug Administration (“FDA”) regulation that currently prevents using CO with meat packaging systems in the United States is 21 C.F.R. § 173.350.

The food additive combustion product gas may be safely used in the processing and packaging of the foods designated in paragraph (c) of this section for the purpose of removing and displacing oxygen...(b) The food additive meets the following specifications: (1) Carbon monoxide content not to exceed 4.5 percent by volume...(c) It [carbon monoxide] is used or intended for use to displace or remove oxygen in the processing, storage, or packaging of beverage products and other food, except fresh meats.

Exhibit D (emphasis added); *see* also DelDuca Decl. ¶ 9.

The concern of the FDA is believed to be that CO fixes the fresh meat color to a degree that allows the retailer to sell meat that looks good (a bright red color), but is unsafe and potentially dangerous to consume because it has unacceptable levels of bacteria. DelDuca Decl. ¶ 10.<sup>3</sup> This act of fixing the meat color to a bright red color is referred to as “economic adulteration.” DelDuca Decl. ¶ 10.

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<sup>1</sup> 21 U.S.C. § 121.1060 was first promulgated on August 2, 1961 (Exhibit B) and permitted the use of combustion product gas containing up to 4.5% CO for use “to displace or remove oxygen or remove oxygen in the processing, storage, or packaging of citrus products, vegetable fats and vegetable oils, coffee, and wine.” In December 14, 1962, 21 U.S.C. § 121.1060 (Exhibit C) was amended to exclude fresh meats. In March of 1977, 21 U.S.C. § 121.1060 was re-designated as 21 C.F.R. § 173.350.

<sup>2</sup> *See also* DelDuca Decl. ¶ 9.

<sup>3</sup> *See, e.g.,* Exhibit E (In a 1962 letter, the FDA told a Whirlpool representative that it might need additional data “to establish that the treatment of meat would not serve to cause the meat to retain its fresh red color longer than meat not so treated” and that the FDA has a question “concerning possible deception of the consumer where treatment of the meat leads to longer retention of the fresh red color.”).

**ii. Problem Addressed in Present Invention**

After about 40 years of not allowing CO to be used with fresh meats in the United States, the Applicants came up with novel approaches of using CO in modified atmosphere packaging (MAP) systems that avoided the concerns of “fixing” the meat color. DelDuca Decl. ¶ 11. The present invention does not “fix” the color of the meat pigment to red with its use of CO, but rather the meat pigment tends to turn brown in a natural time period. See DelDuca Decl. ¶ 6; page 12, lines 10-12 of the application. It is important to prevent the meat color from being “fixed” because it is unsafe (and potentially dangerous) to consume a piece of meat that has a bright red color that consumers associate with freshness, but has an unacceptable amount of bacteria. *Id.* at ¶ 6. Thus, the present invention addresses the concern of the FDA of CO that fixes the fresh meat color to a degree that allows the retailer to sell meat that looks good (a bright red color), but is unsafe and potentially dangerous to consume because it has unacceptable levels of bacteria.

Thus, a problem of fixing meat color with CO that was recognized for at least the last 40 years is overcome by the modified atmosphere packages and methods of manufacturing the same. See, e.g., DelDuca Decl. ¶ 11. This is evidence that the present invention, which solved the problems presented with CO, is not obvious. See, e.g., *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1380-1382 (Fed. Cir. 1986) (That the claimed invention solved longstanding problems supported the conclusion of nonobviousness) and also *In re Rothermel*, 276 F.2d 393, 397 (1960) (the nature of the problem “which persisted in the art” and the inventor’s solution, are factors to be considered in determining whether the invention would have been obvious to a person of ordinary skill in that art).

Therefore, in addition to the applied references not presenting a *prima facie* case, the Applicants also believe that the present invention is allowable because of the compelling evidence of non-obviousness. Therefore, independent claims 38 and 76 are believed to be allowable over the applied references of Woodruff, Stockley, Sorheim, or any combination thereof.

**D. Dependent Claims 39-56 and 77-86**

In dependent claims 50 and 53, further references were applied in combination with Woodruff, Stockley, and Sorheim. Neither U.S. Patent No. 3,459,117 to Koch (“Koch”) nor DE

1935566 to Verbruggen (“Verbruggen”) addresses the deficiencies in the previously applied references of Woodruff, Stockley, and Sorheim. Dependent claims 39-56 and 77-86, which depend directly or indirectly on independent claim 38 or 76, are believed to be allowable over Woodruff, Stockley, Sorheim, Koch, Verbruggen or any combination thereof for at least the same reasons as discussed with respect to claims 38 and 76.

**E. Independent Claims 87 and 103**

Independent claims 87 and 103 recite, *inter alia*, “sealing the layer substantially impermeable to oxygen to the package”, “removing the layer substantially impermeable to oxygen”, “sealing a layer having at least a portion being substantially permeable to oxygen”, and a low oxygen environment that includes from about 0.1 to about 0.8 vol.% CO. Independent claims 87 and 103 are believed to be allowable over the references of Woodruff, Stockley, Sorheim or any combination thereof for at least the same reasons as discussed above with respect to claims 38 and 76. Dependent claims 88-102 and 104-118, which depend directly or indirectly on independent claim 87 or 103, are believed to be allowable over Woodruff, Stockley, Sorheim, Koch, Verbruggen, or any combination thereof for at least the same reasons as discussed with respect to claims 38 and 76.

**F. Independent Claims 119, 138, and 157**

For example, independent claims 119, 138, and 157 recite, *inter alia*, “a first layer having at least a portion being substantially permeable to oxygen”, “a second layer being substantially impermeable to oxygen,” and a low oxygen environment that includes from about 0.1 to about 0.8 vol. % carbon monoxide (CO). Independent claims 119, 138, and 157 are believed to be allowable over the references of Woodruff, Stockley, Sorheim or any combination thereof for at least the same reasons as discussed above with respect to claims 38 and 76. Dependent claims 120-137, 139-156, and 158-168, which depend directly or indirectly on independent claim 119, 138, or 157, are believed to be allowable over Woodruff, Stockley, Sorheim, Koch, Verbruggen, or any combination thereof for at least the same reasons as discussed with respect to claims 38 and 76.




**G. Conclusion**

The Applicants submit that the claims are in a condition for allowance and action toward that end is earnestly solicited. The Applicants have enclosed a check in the amount of 2,240.00. It is believed that no further fees are due; however, should any additional fees be required (except for payment of the issue fee), the Commissioner is authorized to deduct the fees from Jenkins & Gilchrist, P.C. Deposit Account No. 10-0447, Order No. 47097-01106USC1.

Respectfully submitted,

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Date

  
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